Putrescent Whole Egg Solids
Final Work Plan
Registration Review Case Number: 4079

Approved By:

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Docket Number: EPA-HQ-OPP-2010-0726

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Final Work Plan (FWP) for Putrescent Whole Egg Solids (Case 4079). The FWP includes the expected registration review timeline. The work plan also addresses public comments received concerning the Preliminary Work Plan in the Summary Document, which was posted in the Putrescent Whole Egg Solids registration review docket (EPA-HQ-OPP-2010-0726), and any other comments concerning the initial docket postings. The Summary Document provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. Changes in science, public policy, and pesticide use practices will occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet that statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at http://www.epa.gov/oppsrrd1/registration_review/.

The Putrescent Whole Egg Solids Preliminary Work Plan was entered into the docket for this registration review on September 29, 2010. The 60-day comment period ended on November 29, 2010. The Preliminary Work Plan document is available on www.regulations.gov; docket number EPA-HQ-OPP-2010-0726.

Products containing the active ingredient Putrescent Whole Egg Solids were first registered by the Agency in May 1975. Currently, there are 16 registered end-use products that contain Putrescent Whole Egg Solids as an active ingredient; 9 of these products contain other active ingredients, while the other 7 contain Putrescent Whole Egg Solids as the sole active ingredient. There are no manufacturing-use products containing this active ingredient registered by the Agency at this time.

Putrescent Whole Egg Solids are produced from eggs that the United States Department of Agriculture has declared inedible for human consumption due to cracked shells, excessive blood spots or other imperfections not conforming to the standards set for food use. Pesticide products, containing Putrescent Whole Egg Solids as an active ingredient, are registered for use as animal repellents and fly attractants.

Putrescent Whole Egg Solids are exempt from the requirement of a tolerance under 40 CFR 180.1071(a):

§ 180.1071 Peanuts, Tree Nuts, Milk, Soybeans, Eggs, Fish, Crustacea, and Wheat; exemption from the requirement of a tolerance.

(a) *General.* Residues resulting from the following uses of the food commodity forms of peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, and wheat are exempted from the requirement of a tolerance in or on all food commodities under FFDCA section 408 (when used as either an inert or an active ingredient in a pesticide formulation), if such use is in accordance with good agricultural practices:

(1) Use in pesticide products intended to treat seeds.
(2) Use in nursery and greenhouse operations, as defined in 40 CFR 170.3, which includes seeding, potting and transplanting activities.
(3) Pre-plant and at-transplant applications.
(4) Incorporation into seedling and planting beds.
(5) Applications to cuttings and bare roots.
(6) Applications to the field that occur after the harvested crop has been removed.
(7) Soil-directed applications around and adjacent to all plants.
(8) Applications to rangelands, which is land, mostly grasslands, whose plants can provide food (*i.e.*, forage) for grazing or browsing animals.
(9) Use in chemigation and irrigation systems (via flood, drip, or furrow application with no overhead spray applications).
(10) Application as part of a dry fertilizer on which an active ingredient is impregnated.
(11) Aerial and ground applications that occur when no above-ground harvestable food commodities are present (usually pre-bloom).
(12) Application as part of an animal feed-through product.
(13) Applications as gel and solid (non-liquid/non-spray) crack and crevice treatments that place the gel or bait directly into or on top of the cracks and crevices via a mechanism such as a syringe.
(14) Applications to the same crop from which the food commodity is derived, whether the plant fraction(s) intended for harvest are present or not, *e.g.*, applications of peanut meal when applied to peanut plants.

[70 FR 1360, Jan. 7, 2005]

II. SUMMARY OF COMMENTS RECEIVED ON PRELIMINARY WORK PLAN

The Agency received no comments on the Summary Document and Preliminary Work Plan from registrants or the public during the comment period. The anticipated data needs, work plan and timeline described in the Preliminary Work Plan remain as they were presented initially.

In the Preliminary Work Plan, the Agency solicited comments on three specific topics: environmental justice, water body impairment, and trade irritants. No comments or information were received during the comment period concerning these issues. This document makes final the work plan for the Putrescent Whole Egg Solids registratiou review process.

III. RISK ASSESSMENT AND DATA NEEDS

Product Chemistry

All product chemistry data requirements for Putrescent Whole Egg Solids have been satisfied. Assessment of these data shows that they continue to meet the standard for registration under FIFRA, as amended by the FQPA. No further product chemistry data are expected to be required. Please refer to the Putrescent Whole Egg Solids Chemistry Scoping Document posted in the initial docket (EPA-HQ-OPP-2010-0726) for a more detailed discussion and as summarized in Tables 1 and 2 below.

TABLE 1. Product Identity, Composition, Analysis, and Certified Limits of *Putrescent Whole Egg Solids* (40 CFR 158.2030)

OCSPP Guideline No.	Study	Results
880.1100	Product Identity and Composition	Data requirements have been satisfied (CBI).
880.1200	Description of Starting Materials, Production and Formulation Process	
880.1400	Discussion of Formation of Impurities	
830.1700	Preliminary Analysis	
830.1750	Certification of Limits	
830.1800	Enforcement Analytical Method	

TABLE 2. Physical and Chemical Properties of *Putrescent Whole Egg Solids* (40 CFR 158.2030)			
OCSPP Guideline No.	**Property**	**Description of Result**	**MRID**
830.6302	Color	Light brown, beige	42072103 47396912
830.6303	Physical State	Powder	42072103 47396912
830.6304	Odor	Slightly "malty"	42072103
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Decomposes when exposed to air, moisture, etc.	42072103
830.6315	Flammability	Does not contain combustible liquids	47396912
830.6317	Storage Stability	Not required for TGAI	
830.6319	Miscibility	Not required for TGAI	
830.6320	Corrosion Characteristics	Not required for TGAI	
830.7000	pH	6.4	42072103
830.7050	UV/Visible Light Absorption	Not anticipated as being needed to be required based on known physical and chemical properties of the a.i.	
830.7100	Viscosity	N/A; the TGAI is a solid.	
830.7200	Melting Point/Range	When heat is applied to the substance, it gradually changes color from light brown to black (decomposition) before melting of the powder can be observed.	47417801
830.7220	Boiling Point/Range	Not anticipated as being needed to be required as the TGAI is not a liquid at room temperature (refer to test note #14 of 40 CFR 158.2030(e))	
830.7300	Density	0.514 g/ml	47417801
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not anticipated as being required based on known physical and chemical properties of the a.i.	

830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Not required based on known physical and chemical properties of the a.i.	
830.7840	Water Solubility	Practically insoluble in water	42072103 47417801
830.7950	Vapor Pressure	Not anticipated as being required based on known physical and chemical properties of the a.i.	

Human Health Risk Assessment

Based on available data and information, the Agency does not foresee the need for new data or for a new human health risk assessment for this active ingredient. Hazard and exposure information, as well as Agency risk assessments on Putrescent Whole Egg Solids, were evaluated against current safety standards established by the Agency's scientific policies and regulations, and it was determined that there is no need to conduct an additional human health risk assessment. Fresh eggs and egg products are Generally Recognized as Safe (21 CFR 170.3) by the Food and Drug Administration, while egg solids are recognized as a common human food or significant component of common human food.

Available Putrescent Whole Egg Solids toxicity data, as required by 40 CFR 158.2050, are summarized below (see Tables 3–8). Please refer to the Putrescent Whole Egg Solids Preliminary Human Health Assessment, which is posted in the docket (EPA-HQ-OPP-2010-0726), for more detailed discussion.

Table 3. Putrescent Whole Egg Solids: Acute Oral Toxicity/OCSPP870.1100

LD_{50}	Toxicity Category	MRID
>5,000 mg/kg	IV	46295003
Adequate information submitted to support data requirement	IV	47417806
>5,000 mg/kg	IV	46032706
>5,000 mg/kg	IV	47357705

Table 4. Putrescent Whole Egg Solids: Acute Dermal Toxicity/OSCPP 870.1200

LD_{50}	Toxicity Category	MRID
>2,000 mg/kg*	III*	42693802
>5,000 mg/kg	IV	46295004
>2,000 mg/kg*	III*	47417807
>5,000 mg/kg	IV	46032707
>5,000 mg/kg	IV	47357706

* 2,000 mg/kg was the highest dose tested in the study.

Table 5. Putrescent Whole Egg Solids: Acute Inhalation Toxicity/OSCPP 870.1300

LC_{50}	Toxicity Category	MRID
>2.10 mg/L	IV	46295005
>2.08 mg/L	IV	47417808
>2.08 mg/L	IV	46032708

Table 6. Putrescent Whole Egg Solids: Acute Eye Irritation/OSCPP 870.2400

Results	Toxicity Category	MRID
Corneal irritation clearing within 7 days or less	III	46295006
Corneal irritation clearing within 48 hours	III	47417809
Corneal irritation clearing within 4 days	III	43311401
Corneal irritation clearing within 72 hours	III	46032709
Corneal irritation clearing within 48 hours	III	47357709

Table 7. Putrescent Whole Egg Solids: Acute Dermal Irritation/OSCPP 870.2500

Results at 72 hrs	Toxicity Category	MRID
Slight irritation	IV	46295007
Slight irritation	IV	47417810
Slight irritation	IV	43311402
Moderate irritation	III	46032710
Slight irritation	IV	47357710

Table 8. Putrescent Whole Egg Solids: Skin Sensitization/OSCPP 870.2600

Results	MRID
0.4 mL Is a Skin Sensitizer	46295008
Not a Sensitizer	47417811
Is a Skin Sensitizer*	46032711
Not a Sensitizer	47357711
Is a Skin Sensitizer*	47357712

*Putrescent Whole Egg Solids was not the only active ingredient in these products.

Incidents Assessment

According to the Incident Data System, ten reported incidents occurred between September 30, 2008 and May 31, 2009 from the use of EPA-registered products containing Putrescent Whole Egg Solids as their active ingredient. One incident was attributable to product misuse but no details on the incident were received. One incident was attributable to human inhalation exposure. Four incidents were attributable to domestic animal incidents, in which dogs ingested small amounts of product and some resulted in diarrhea. The remaining four incidents were attributable to plant damage. Upon reviewing these incidents, the Agency has determined that unreasonable adverse effects on the environment are not likely when Putrescent Whole Egg Solids-containing products are used in accordance with their respective labels.

Environmental Fate and Ecological Risk Assessment

1. Effects on Nontarget Organisms

All nontarget toxicity data requirements for Putrescent Whole Egg Solids have been satisfied and meet the standard for registration required under FIFRA, as amended by FQPA. The Agency has completed this assessment and concluded that exposure to Putrescent Whole Egg Solids will not result in hazard or toxic risk to nontarget organisms. Please refer to the Putrescent Whole Egg Solids Ecotoxicity Assessment, which is posted in the docket (EPA-HQ-OPP-2010-0726), for more detailed discussion.

2. Endangered Species Assessment

The Agency has conducted a risk assessment that supports a complete endangered species determination. Not only is there low potential for exposure to Putrescent Whole Egg Solids, but this active ingredient also degrades quickly in the environment and is not toxic to nontarget organisms. Given this information, the Agency has determined that the registered uses of Putrescent Whole Egg Solids will have "No Effect" on endangered and threatened terrestrial or aquatic species, or any designated critical habitat, as listed by the United States Fish and Wildlife Service and the National Marine Fisheries Service. Please refer to the Putrescent Whole Egg Solids Ecotoxicity Assessment, which is posted in the docket (EPA-HQ-OPP-2010-0726), for more detailed discussion.

IV. Endocrine Disruptors

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), Putrescent Whole Egg Solids are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. Putrescent Whole Egg Solids are not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Accordingly, as part of registration review, EPA will issue future EDSP orders/data call-ins, requiring the submission of EDSP screening assays for Putrescent Whole Egg Solids. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

V. ESTIMATED TIME

EPA has created the following estimated timeline for completion of the Putrescent Whole Egg Solids Registration Review Case:

Activities	Estimated Month/Year
Phase 1: Opening the Docket	
Open Public Comment Period for Putrescent Whole Egg Solids	September 2010
Close Public Comment Period	November 2010
Phase 2: Case Development	
Issue Final Work Plan (FWP)	March 2011
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Final Decision	September 2011
Close Public Comment Period	November 2011
Publish Registration Review Final Decision and Begin Post-Decision Follow-Up	December 2011
*Estimated Total (years)	1 year, 3 months

* This schedule is subject to revision should unforeseen issues arise during the registration review process.

VI. NEXT STEPS

EPA expects to issue a Proposed Registration Review Final Decision for public comment in September 2011.